

UNITED STATES DEFARIMENT OF COMME United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignia 22313-1450 www.uspto.gov

FILING OR 371 APPL NO. **ART UNIT** FIL FEE REC'D ATTY.DOCKET NO **DRAWINGS TOT CLMS** IND CLMS (c) DATE 10/550,998 10/24/2005 1614 1030 TOYA117.005APC 13 8 3

CONFIRMATION NO. 1401

FILING RECEIPT

OC000000018267319

20995 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET **FOURTEENTH FLOOR IRVINE, CA 92614**

Date Mailed: 03/17/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Tadahiko Kato, Tokyo, JAPAN: Akira Asari, Musashino-shi, JAPAN:

Power of Attorney: The patent practitioners associated with Customer Number 20995.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP04/04240 03/25/2003

Foreign Applications

JAPAN 2003-083831 03/25/2003

Projected Publication Date: 06/22/2006

Non-Publication Request: No

Early Publication Request: No

Title

Remedy for nerve damage... Therapeutic Agent for Nerve Damage 514

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

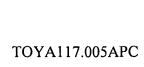
This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject

matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Kato, et al.

Appl. No.

10/550,998

Filed

October 24, 2005

For

THERAPEUTIC AGENT FOR

NERVE DAMAGE

Examiner

Unknown

20113, WOG

Group Art Unit 1614

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

April 13, 2006

(Date)

Che Swyden Chereskin, Ph.D., Reg. No. 41,466

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
P.O. Box 1450
Office of Initial Patent Examination
Customer Service Center
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby request that the Official Filing Receipt, a copy of which is enclosed, be changed to reflect the correct title of the invention. The title was amended in a preliminary amendment filed with the application on October 24, 2005. The title should be THERAPEUTIC AGENT FOR NERVE DAMAGE. Presently, it is Remedy for nerve damage. Supporting documentation for the requested change is provided herewith.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

By:

Che Swyden Chereskin, Ph.D.

Registration No. 41,466

Agent of Record

Customer No. 20,995

(949) 760-0404



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Kato, et al.

Int'l Appl. No.

PCT/JP2004/004240

Int'l filing date

March 25, 2004

For

THERAPEUTIC AGENT FOR

NERVE DAMAGE (amended)

Examiner

unknown

Group Art Unit

unknown

PRELIMINARY AMENDMENT

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Preliminary to examination on the merits, please amend the above-captioned U.S. application as follows.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 4 of this paper.

Int'l Appl. No.

PCT/JP2004/004240

Int'l filing date

March 25, 2004

AMENDMENTS TO THE SPECIFICATION

Please change the title as follows:

REMEDY THERAPEUTIC AGENT FOR NERVE DAMAGE

On page 1 of the Specification, after the Title of the Invention and before the Technical Field starting on line 1, please insert the following section:

Related Applications

This application is the U.S. National Phase under 35 U.S.C. § 371 of International Application PCT/JP2004/004240, filed March 25, 2004, which was published in a language other than English, which claims priority of Japanese Patent Application No. 2003-083831, filed March 25, 2003.

On page 16 before Claim 1, please amend as follows:

WHAT IS CLAIMED IS: CLAIMS

Please amend the abstract as shown:

The present invention provides a therapeutic agent for nerve damages such as those caused by spinal cord injury or nerve trauma, which comprises includes, as an active ingredient, a low-molecular-weight saccharide composed of at least glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof. The present invention also provides a therapeutic agent for nerve damages which comprises includes, as an active ingredient, preferably a low-molecular-weight hyaluronic acid, more preferably hyaluronic acid disaccharide to hyaluronic acid 2,500-saccharide, further more preferably hyaluronic acid disaccharide to hyaluronic acid 50-saccharide, much more preferably hyaluronic acid tetrasaccharide, or a pharmaceutically acceptable salt thereof.

Int'l Appl. No.

PCT/JP2004/004240

Int'l filing date

March 25, 2004

AMENDMENTS TO THE CLAIMS

- 1. (Currently Amended) A therapeutic agent for nerve damage comprising, as an active ingredient, a low-molecular-weight saccharide emposed-of at leastcomprising glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof.
- 2. (Currently Amended) The therapeutic agent according to claim 1, wherein the low-molecular-weight saccharide eomposed at-least glucuronic acid and/or N acetylglucosamine-is a low-molecular-weight hyaluronic acid.
- 3. (Original) The therapeutic agent according to claim 2, wherein the low-molecular-weight hyaluronic acid is hyaluronic acid disaccharide to hyaluronic acid 2,500-saccharide.
- 4. (Original) The therapeutic agent according to claim 3, wherein the low-molecular-weight hyaluronic acid is hyaluronic acid disaccharide to hyaluronic acid 50-saccharide.
- 5. (Original) The therapeutic agent according to claim 4, wherein the low-molecularweight hyaluronic acid is hyaluronic acid tetrasaccharide.
- 6. (Currently Amended) The therapeutic agent according to any one of claims 1 to 5claim 1, wherein nerve damage is caused by spinal cord injury or nerve trauma.
- 7. (Currently Amended) A method of treating nerve damage, comprising administering an effective amount of a low-molecular-weight saccharide eomposed of comprising at least glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof to an animal suffering from nerve damage.
- 8. (Currently Amended) A method of manufacturing a therapeutic agent for nerve damageUse of which comprises dissolving a low-molecular-weight saccharide composed of at leastcomprising glucuronic acid and/or N-acetylglucosamine or a pharmaceutically acceptable salt thereof in a solvent commonly used for drugsmanufacturing a therapeutic agent for nerve damage.

Int'l Appl. No.

PCT/JP2004/004240

Int'l filing date

:

March 25, 2004

REMARKS

The claims have been amended to conform with the rules of practice before the U.S. Patent and Trademark Office. The specification has been amended to recite the International Application and priority application. The word "CLAIMS" has been deleted and substituted by "WHAT IS CLAIMED IS" so that subsequently appearing claims will be the object of a sentence as specified by M.P.E.P. section 608.01(m). The Abstract has been amended to remove legal language. As a result of this preliminary amendment, Claims 1-2 and 6-8 have been amended. Support for the amendment to claim 8 is found in the present specification at page 8, lines 9-11. Accordingly, Claims 1-8 are presented for examination. No new matter is being added herewith.

Conclusion

Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 26 2005

By:

Che Swyden Chereskin, Ph.D.

Registration No. 41,466

Agent of Record

Customer No. 20,995

(949) 760-0404

1942295 092005